

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: Bair Hugger Forced Air Warming
Devices Products Liability Litigation

MDL No. 15-2666 (JNE/DTS)

**DEFENDANTS' RESPONSE
TO THE COURT'S
MAY 6, 2019 ORDER**

This Document Relates To:
ALL ACTIONS

Defendants respond here to the questions the Court posed in the May 6, 2019 Order.

MDL ECF No. 1905.

RESPONSES

**I. PLAINTIFFS' EXPERTS DO NOT FOLLOW ANY RELIABLE
METHODOLOGY FOR RULING OUT ALTERNATIVE CAUSES.**

As Defendants and their experts have demonstrated, periprosthetic joint infections (PJIs) may be caused by a myriad of sources – the vast majority occurring without any identifiable source. Foremost among the known sources is bacteria that reside on the patient's own skin, followed by bacteria that travel within the patient's bloodstream ("hematogenous spread"). To the extent a PJI is caused by airborne pathogens, there are many things in the operating room that can affect air currents, including the movement of surgical personnel, opening and closing of doors, and use of common surgical devices that generate air currents and/or heat. PJIs may also be caused after the surgery, by (for example) inadequate wound care or bacteria entering the wound before it has fully healed. Accordingly, the Court first asks: "[G]iven all the possible causes of Plaintiffs' infections, what scientifically reliable process or methodology could Plaintiffs use to eliminate likely

causes and identify the Bair Hugger as the most probable cause of infection and how does this process or methodology satisfy *Daubert*.” Order at 2.

Defendants have not found within the mainstream scientific literature any methodology for identifying the most probable cause of a PJI and ruling out alternative causes that *has* passed *Daubert* muster. Defendants are aware, however, of two methodologies employed by reputable scientific investigators in the real world of patient care that potentially *could* satisfy *Daubert*. The first is genome sequencing (sequencing and analysis of bacterial cell DNA), a newer approach that allows the infection to be traced to a specific source, such as a particular medical device. The second is the Centers for Disease Control’s so-called “gold standard” for investigating outbreaks, which requires a rigorous investigation of the care provided by the hospital and application of multivariate statistical analysis that considers all potential causes. Either methodology could potentially satisfy *Daubert* in this litigation because each has the capacity to isolate the source of the infection and allow the ruling out of alternative causes, including the patient’s own medical characteristics, other medical devices, and surgical techniques.

Plaintiffs have used neither methodology. Instead, Plaintiffs’ methodology, exemplified by Dr. Jarvis’s purported application of the Bradford Hill method at the *Gareis* trial, does not either reliably rule in the Bair Hugger system or rule out the main alternative possible causes of each individual’s PJI.¹

¹ Dr. Jarvis’s opinion in *Trombley* confirms that he will always conclude that the Bair Hugger most probably caused any plaintiff’s PJI, no matter the circumstances. In that case, there was no dispute that the plaintiff’s PJI was caused by Group B *Streptococcus* (GBS).

A. Genome Sequencing and the CDC’s “Gold Standard” for Outbreak Investigations Are Possible Methods for Isolating the Cause of Post-Surgical Infections and Ruling Out Alternative Causes.

The CDC is charged with investigating outbreaks of post-surgical infections. It has used two methods to determine the cause of infections: more recently, genome sequencing, and historically, the so-called “gold standard” of rigorous epidemiological investigation.

Genome sequencing. The Court has heard some information about the CDC’s heater-cooler investigation earlier in this litigation. That investigation involved an outbreak of *M. chimaera* following heart surgeries. The CDC undertook whole genome sequencing of *M. chimaera* bacteria taken from the wounds of infected patients and from heater-cooler devices, and was able to match them – that is, the CDC was able to trace the bacteria-causing infections to specific medical devices. Hulse 3d Recon. Decl. DX20, FDA Oct. 13, 2016 Safety Communication.² Here, this would involve culturing bacteria from the wounds of infected individuals, culturing bacteria from Bair Hugger devices, and conducting genome sequencing to see whether they match.

GBS is typically found in the gut, rectum, urinary tract or vaginal tract. Def. Mot. to Exclude Jarvis, *Trombley*, 16-cv-4159, ECF No. 42, at 4. Dr. Jarvis conceded that GBS does not generally live on skin and did not dispute that GBS is not commonly transmitted though the air. *Id.* at 5. He further admitted that GBS can travel through a person’s blood to other parts of the body and cause infections elsewhere. *Id.* Moreover, based on the characteristics of the PJI, the plaintiff’s own surgeon concluded that it was most likely caused after the surgery. *Id.* at 4-5. Jarvis ignored or minimized all these facts in blaming the Bair Hugger system for the plaintiff’s PJI.

² The Third Declaration of Benjamin W. Hulse in Support of Defendants’ Motion for Reconsideration of the Court’s December 113, 2017 Order on General Causation has been filed contemporaneously with this Response.

The “gold standard” for epidemiological investigations. Before he became a litigation expert for Plaintiffs, Dr. Jarvis used CDC’s “gold standard” epidemiological method to investigate an unusual outbreak of infections following knee replacement surgeries at a Tennessee hospital. Hulse Med. Experts Decl. DX20, MDL ECF No. 751, Gordon, Jarvis, et al., “Risk Factors for Wound Infections After Total Knee Arthroplasty,” 131:5 *Am. J. Epidemiology* 905 (1990). The investigation looked at 20 infections over just under four years, 18 of which were PJIs. Hulse Med. Experts Decl. DX5, Jarvis Dep., MDL ECF No. 751 at 205:2-206:19. The CDC had been called in to investigate this unusual rate of infections by the hospital epidemiologist, who suspected that they were clustered around one surgeon. *Id.* at 209:7-210:1. The CDC examined records, conducted interviews of medical personnel, and compiled data on, among other things, the type of knee prosthesis implanted, whether it was fixed with cement or cementless, the number of personnel in the OR during surgery, the presence of assisting surgeons, whether there were intraoperative irrigations, the duration of post-operative wound drains, the use of antimicrobial prophylaxis, the timing of the first dose of antimicrobial prophylaxis relative to skin incision, the total duration of the operation, the use of an intraoperative limb tourniquet, preoperative shaving, identity of the surgeon, use of a continuous passive motor machine after surgery, duration of post-operative fever, duration of antimicrobial exposure or administration, time between surgery and documentation of infection, wound culture results, and time between initial procedure and first reoperation. *Id.* at 215:11-223:21.

The CDC examined each of these factors because each factor could potentially have an impact on the PJI rate. *Id.* at 223:16-21. Having gathered extensive information on

multiple possible factors that could have impacted infection rates, Dr. Jarvis and his colleagues then performed a series of multivariate analyses to isolate any factors that were associated with a significant impact. *Id.* at 227:15-228:12. Through this process, they isolated two significant factors in addition to the particular surgeon: the patient's ASA score (a measure of the patient's fitness for surgery) and use of the continuous passive motion machine. *Id.* at 228:14-229:1.

None of Plaintiffs' experts, Dr. Jarvis included, has followed either methodology in this litigation. They have not employed genome sequencing to attempt to trace specific bacteria to specific Bair Hugger warming units. They have not collected, much less analyzed, data on surgical practices and infection rates at each hospital. They do not look to see, for example, whether particular doctors have higher infection rates than others, or whether there are surgical practices or other equipment that are more frequently associated with infections. Rather, based on the Observational Study and review of the Plaintiff's medical records, they find the Bair Hugger system always to be the most probable cause, and avoid collecting or reviewing data that might tell them otherwise.

B. Dr. Jarvis's Methodology Fails to Account for Multiple Plausible Causes of Joint Infections.

Plaintiffs' built-for-litigation methodology falls far short of the rigorous approaches followed by the CDC, and far short of *Daubert's* requirements. While an expert is not required to rule out all possible causes of an injury, the expert should nevertheless "adequately account[] for obvious alternative explanations." *Redd v. DePuy Orthopaedics, Inc.*, 700 Fed. Appx. 551, 554 (8th Cir. 2017). An obvious problem with Plaintiffs' experts'

approach is that infections regularly occur in knee and hip surgeries when the Bair Hugger system is *not* used. PJIs are not a signature condition of exposure to the Bair Hugger system. Dr. Jarvis has admitted that infections occur in “lots and lots” of surgeries where the Bair Hugger is not used. Hulse 3d Recon. Decl. DX22, Jarvis Dep. (*Gareis*) at 74:6-11. Indeed, the Observational Study reported infections in knee and hip surgeries where the Augustine HotDog was used.³ Hulse 1st Recon. Decl. DX1, MDL ECF No. 1720, at 1542 & Table II.

Plaintiffs and their experts have never explained why infections commonly occur in non-Bair Hugger surgeries. They have not analyzed the medical records from any such cases. According to the presumptions underlying Dr. Jarvis’s methodology, there must have been medical malpractice in every one of those cases, or the infection would not have occurred. Because they have failed to explain how infections occur in these non-Bair Hugger cases, Plaintiffs cannot demonstrate in *any* case that the infection would not have occurred but for the use of the Bair Hugger system.

Case law strongly supports the conclusion that Plaintiffs cannot meet their burden of proof in any case. Courts have repeatedly held that a differential diagnosis cannot find that the defendant’s product is the most probable cause where a medical injury commonly occurs without exposure to the defendant’s product. For example, in *Bland v. Verizon*

³ As Dr. Reed testified, the actual infection rate for the HotDog period was higher than reported in the published Observational Study. Hulse Med. Experts Decl. DX8, Reed Dep., MDL ECF No. 751 at 42:23-44:9. One of the four HotDog infections “disappeared” while the data was being analyzed by Dr. Augustine’s biostatistician.

Wireless (VAW) L.L.C., 538 F.3d 893, 897 (8th Cir. 2008), the plaintiff’s expert concluded, based on a differential diagnosis, that freon exposure was the most probable cause of the plaintiff’s exercise-induced asthma, even though the cause of exercise-induced asthma is unknown in the majority of cases. The Eighth Circuit affirmed exclusion of the expert’s opinion: “As a practical matter, Dr. Sprince’s causation opinion could not possibly be based upon a reasonable degree of medical certainty.” *Id.* Here, too, Dr. Jarvis (or Plaintiffs’ other experts) cannot isolate the Bair Hugger system as the most probable cause of any individual’s infection to a reasonable degree of medical certainty, and cannot rule out idiopathic causation.

Likewise, in *Hall v. Conoco Inc.*, 886 F.3d 1308, 1314 (10th Cir. 2018), the Tenth Circuit affirmed exclusion of a causation expert who failed to adequately rule out an idiopathic cause of the plaintiff’s acute myeloid leukemia. *Id.* (“This omission concerned the district court because the evidence had pointed to idiopathic causes in most cases of acute myeloid leukemia, and the district court could reasonably view the failure to rule out idiopathic causes as a fatal error tainting the differential diagnosis.”). In *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010), the Sixth Circuit affirmed exclusion of the plaintiff’s causation expert because idiopathic causation was “impossible to ignore and difficult to rule out.”⁴

⁴ Plaintiffs may argue that the Observational Study’s risk ratio is high enough, by itself, to establish specific causation. The Fourth Circuit recently rejected this argument in the Lipitor MDL: “That Lipitor may cause an increased risk of diabetes notwithstanding certain other risk factors is insufficient to conclude that the drug was a substantial contributing factor in an individual patient. To hold otherwise would obviate the need for

Moreover, due to the background risk of infection, the Observational Study data do not, in fact, support an association between the Bair Hugger system and increased PJI risk. Those data may show only an association between the Bair Hugger system and *less-decreased* risk. As Dr. Borak notes, “[e]ven if there were sufficient evidence to conclude a difference between two alternative warming methods, it would not necessarily indicate that the inferior method ‘caused’ the adverse outcomes (i.e., SSI). Instead, it might be a question of the relative efficacies of two beneficial methods.” Hulse Med. Experts Decl. DX9, Borak Rpt., MDL ECF No. 751 at 4 n.1.

Because there has not been a consistently reported association between Bair Hugger use and infections, the medical and scientific community has rejected the causation inferences made by Plaintiffs’ experts in this litigation. In 2017, the FDA reviewed available data and literature, was “unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection,” and continued to recommend use of forced air warming systems.⁵ In 2018, the International Consensus Meeting on Musculoskeletal Infection (“ICM”) reached a strong consensus (93% agree, 2% disagree, 5% abstain) that “[t]here is no evidence to definitively link [forced air warming] to an increased risk of SSIs/PJIs.” Hulse 1st Recon. Decl. DX2, 2018

any specific causation evidence at all.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 892 F.3d 624, 644 (4th Cir. 2018).

⁵ “Information about the Use of Forced Air Thermal Regulating Systems - Letter to Health Care Providers” (Aug. 30, 2017), online at <https://www.fda.gov/medical-devices/letters-health-care-providers/information-about-use-forced-air-thermal-regulating-systems-letter-health-care-providers>.

ICM, MDL ECF No. 1720 at 112. The drafters of the ICM's supporting rationale included Dr. Mike Reed, senior author of the Observational Study and co-author of the Jeans study.

II. THE JEANS (2018) STUDY AND ITS RELEVANCE TO KNEE AND HIP SURGERIES.

A. The Jeans Study Confirms that the Observational Study Was Significantly Confounded and Renders Dr. Samet's Opinion Unreliable.

Next, the Court asks how the Jeans study impacts Dr. Samet's opinion that the Bair Hugger device constitutes a substantial contributing cause of all cases in the MDL. Order at 2. Dr. Samet has not disclosed any opinion on the Jeans study⁶ but, to the extent he does now, he cannot now reliably conclude that the Observational Study supports an inference of causation. Because (as Dr. Samet admitted) the Observational Study provides the only estimate of the risk associated with the Bair Hugger system, the Jeans study renders Dr. Samet's causation opinion unreliable.

As previously discussed in detail in Defendants' Memorandum and Reply, the Jeans study findings confirm that MSSA screening confounded the McGovern Observational Study. The Observational Study used only a univariate statistical analysis, meaning that the effects of potential confounders were ignored. The Jeans study authors employed a multivariate analysis, controlled for confounders, and still found a statistically significant

⁶ Plaintiffs' failure to offer a timely supplemental opinion from Dr. Samet addressing the Jeans study also renders his opinion unreliable. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 426 (S.D.N.Y. 2005) (excluding experts who ignored studies contrary to their opinions and "discussed only the evidence they believed would advance the plaintiffs' position"); *In re Viagra*, 658 F. Supp. 2d 936, 944-45, 950 (D. Minn. 2009) (excluding plaintiff's medical expert based on additional evidence undermining epidemiological study on which the expert relied).

difference in infection rates when MSSA screening was introduced. Hulse 1st Recon. Decl. DX11, MDL ECF No. 1720, Borak *Axline* Rpt. ¶ 21b.

Plaintiffs will likely argue, as they have before, that the Observational Study authors “stand behind their study,” implying that they did not believe it was significantly confounded. But that is not the case. Dr. Reed, senior author of the Observational Study, testified in his 2016 deposition that he was actively investigating whether MSSA screening was a potential confounder. He testified then: “You know, there are other things like MSSA screening which was introduced. But at the time of this paper and still, there is no evidence to say that it reduces infection rates, staph aureus infection rates in joint replacement patients. Now, we are doing a piece of work now that does actually, I think, show that.” Hulse Med. Experts Decl. DX8, Reed Dep., MDL ECF No. 751 at 120:4-10. We now know that the “piece of work” to which Reed referred was the Jeans study. After the Jeans study was published, Reed and his colleagues wrote in *Trials* that “there were significant confounding factors in this study [the Observational Study].” Hulse 2d Recon. Decl. DX16, Kumin et al., MDL ECF No. 1850 at 6. Obviously, Dr. Reed does not “stand behind” the conclusions that Plaintiffs’ experts attempt to draw from the Observational Study. He expressly concedes that there were significant confounders.

Furthermore, the ICM’s recent statement of rationale notes that the Observational Study “did not account for infection control procedures that changed over the study period” and specifically references the Jeans study as one of the “[o]ther studies of the same cohorts by these researchers [which] revealed potential impacts unrelated to the change in warming

modality, including thromboprophylaxis and methicillin-sensitive *Staphylococcus aureus* screening.” Hulse 1st Decl. DX2, MDL ECF No. 1720 at 112 & 114 n.3.

B. The Jeans Study Confirms the Unreliability of Plaintiffs’ Experts’ Opinions as to Both Knee and Hip Surgeries.

The Court next asks what relevance the Jeans study has to hip and knee surgeries. Order at 2. As Dr. Reed has acknowledged, the Jeans study results are relevant to *all* joint replacement surgeries because they demonstrate that the Observational Study was significantly confounded. In reporting that “there were significant confounding factors” in the Observational Study in *Trials*, Dr. Reed did not distinguish between knee and hip surgeries. Hulse 2d Recon. Decl. DX16, Kumin et al., MDL ECF No. 1850 at 6. The ICM’s discussion of confounding factors likewise does not distinguish between knee and hip surgeries. Hulse 1st Recon. Decl. DX2, 2018 ICM, MDL ECF No. 1720 at 112 & n. 3.

While the Court is correct that the decrease in the MSSA infection rate in the Jeans study was predominantly in the *hip* replacement group, that does not mean that the Observational Study reliably supports causation in *knee* replacement cases. On the contrary. The Observational Study data did not demonstrate a statistically significant increase in knee infections in the Bair Hugger group. Table II of the Observational Study sets out the number of knee and hip infections in the HotDog and Bair Hugger groups. There was one knee infection in 236 HotDog surgeries versus nine in 643 Bair Hugger surgeries. These numbers result in a *p*-value of .226607 for the knee infections, a result that

is not statistically significant at $p < .05$.⁷ The Observational Study researchers achieved statistical significance – barely – only by adding together knee and hip infections.

The lack of statistical significance for knee infections is fatal to Plaintiffs' experts' opinions. As Plaintiffs explained in their opposition to Defendants' original *Daubert* motion, their experts applied the Bradford Hill method. Pl. Med. Experts Opp., MDL ECF No. 879 at 39-444. However, "[i]t is well established that the Bradford Hill method used by epidemiologists *does* require that an association be established through studies with statistically significant results." *In re Lipitor*, 174 F. Supp. 3d 911, 924-25 (D.S.C. 2016) (emphasis in original); *see also In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164,

⁷ When the standard Yates correction is applied, the p value is .395147 – even further away from statistical significance. There are multiple statistical significance calculators online, all of which reach comparable results. Defendants used <https://www.socscistatistics.com/tests/chisquare/default2.aspx>, which generates this report:

Chi-Square Calculator

Success! The contingency table below provides the following information: the observed cell totals, (the expected cell totals) and [the chi-square statistic for each cell].

The chi-square statistic, p -value and statement of significance appear beneath the table. Blue means you're dealing with dependent variables; red, independent.

You'll notice we've also calculated a chi-square statistic with the popular Yates correction. There's probably a consensus now that the correction is over-cautious in its desire to avoid a type 1 error, but the statistic is there if you want to use it.

	Developing Infection	Not Developing Infection	Marginal Row Totals
Augustine HotDog	1 (2.68) [1.06]	235 (233.32) [0.01]	236
3M Bair Hugger	9 (7.32) [0.39]	634 (635.68) [0]	643
Marginal Column Totals	10	869	879 (Grand Total)

The chi-square statistic is 1.462. The p -value is .226607. This result is *not* significant at $p < .05$.

The chi-square statistic with Yates correction is 0.723. The p -value is .395147. *Not* significant at $p < .05$.

188 (S.D.N.Y. 2009) (“Several courts that have considered the question have held that it is not proper methodology for an epidemiologist to apply the Bradford Hill factors without data from controlled studies showing an association.”); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 678 (M.D.N.C. 2003) (rejecting expert contention that “it is not necessary to have an epidemiological study that demonstrates an association as a prerequisite for applying the Bradford Hill criteria”). Plaintiffs lack any study showing a statistically significant association between Bair Hugger use and knee PJIs. Thus, if the Court concludes that the Jeans study renders the Observational Study unreliable as to hip surgeries, it must also conclude that the Observational Study does not provide a reliable basis to support Plaintiffs’ experts’ opinions as to knee surgeries.

The Fourth Circuit’s recent opinion in *In re Lipitor*, 892 F.3d 624, 642 (4th Cir. 2018), is instructive. Like Plaintiffs’ medical experts here, the plaintiffs’ causation expert in *Lipitor* reviewed medical literature and then inferred general causation based, purportedly, on application of the Bradford Hill criteria. The district court excluded the expert’s opinion and granted summary judgment because the Bradford Hill criteria require a statistically significant association and the plaintiffs “failed to demonstrate that Dr. Singh’s reliance on non-statistically significant ‘trends’ is accepted in his field, that non-statistically significant findings have served as the basis for any epidemiologist’s causation opinion in peer-reviewed literature, or that standards exist for controlling the technique’s operation.” *Lipitor*, 174 F. Supp. 3d at 926. The Fourth Circuit affirmed, finding that the district court’s conclusion was well within its discretion. *Lipitor*, 892 F.3d at 642.

Here, too, Plaintiffs cannot demonstrate that inferring causation from non-statistically significant data (especially for a single observational study) is accepted in epidemiology or in the peer-reviewed literature. *Lipitor*, 174 F. Supp. 3d at 926 (plaintiffs “failed to demonstrate that Dr. Singh’s reliance on non-statistically significant ‘trends’ is accepted in his field, that non-statistically significant findings have served as the basis for any epidemiologist’s causation opinion in peer-reviewed literature, or that standards exist for controlling the technique’s operation”). As the ICM’s strong consensus demonstrates, the medical community rejects any such causation inference. Nor do Plaintiffs provide a single example of any of their experts relying on non-statistically significant data to find causation in their professional capacities outside the courtroom.

Moreover, as Defendants explained in their original *Daubert* briefing, the Observational Study, properly analyzed, does not in fact achieve statistical significance even when knee and hip infections are combined. As already noted, Dr. Reed has recently acknowledged that “there were significant confounding factors in this study.” Hulse 2d Decl. DX16, Kumin et al., MDL ECF No. 1850 at 6. Indeed, controlling for just the confounders disclosed by the authors, as Defendants’ expert Prof. Holford did, eliminates the “association” between the Bair Hugger system and PJIs. Mark Albrecht, the Augustine employee who performed the data analysis for the Observational Study, also conceded that there is no difference in infection rates when controlling for the disclosed confounders: changes to antibiotic and antithrombotic drug regimens. Hulse Med. Experts Decl. DX12, Albrecht Dep., MDL ECF No. 751 at 200:9-205:18.

Moreover, if the study authors had selected any earlier start date or nearly any later start date for their data set, as they had originally planned to do, they would not have achieved statistical significance. Def. Opp. to Pl. Mot. to Exclude Holford, MDL ECF No. 913 at 25-31. And Dr. Reed testified that the published data were erroneous and in fact there was an additional infection in the HotDog group – an unexplained change to the data that occurred when it was in Augustine’s custody. *Id.* at 12 (citing Hulse Med. Experts Decl. DX8, Reed Dep., MDL ECF No. 751 at 42:23-44:9). Dr. Samet has never reconciled his opinion with Dr. Reed’s testimony or Dr. Holford’s analysis, instead relying on the erroneous published odds ratio.

For all these reasons, the Observational Study’s reported findings do not reliably support Plaintiffs’ allegations involving either hip or knee surgeries.

C. Number of Knee and Hip Surgery Cases in the MDL.

Per the information provided in Plaintiff Fact Sheets, there are 3,037 cases in the MDL involving knee surgeries (primarily but not exclusively total knee replacements) and 1,657 cases involving hip surgeries (primarily but not exclusively total hip replacements). The remaining cases do not involve knee or hip surgeries.

III. PLAINTIFFS LACK RELIABLE EVIDENCE TO ESTABLISH THAT THE BAIR HUGGER WAS THE SOURCE OF INFECTION IN HIP SURGERIES.

Finally, the Court asks what evidence Plaintiffs could rely upon, other than the Observational Study, to establish that the Bair Hugger system was the source of infection. Order at 2. As the Court notes, Dr. Samet testified that “[t]he McGovern [Observational Study] supplies the only estimate of the risk associated for deep joint infection associated

with the use of forced-air warming Bair Hugger device.” Order at 2 n.1, quoting Hulse 1st Recon. Decl. DX9, Samet Dep., MDL ECF No. 1720 at 282:16-23.

Plaintiffs’ three medical causation experts have in fact identified additional statistical evidence of risk, but that evidence likewise does not reliably support causation. In his second deposition, Dr. Samet cited Scott Augustine’s fraudulent 2017 publication as “another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison.” Hulse 2d Med. Experts Decl. DX25, Samet Dep., MDL ECF No. 956 at 30:4-35:13. Dr. Stonnington testified that the Observational Study alone was not “conclusive” proof of causation by itself, but that it was corroborated by Augustine’s study. Hulse 2d Med. Experts Decl. DX26, Stonnington Dep., MDL ECF No. 956 at 119:13-121:23 (testifying regarding McGovern that “you cannot hang your hat on one study” but that “Augustine has also said the same thing”).

Augustine’s data manipulation and misrepresentations are detailed in Defendants’ original *Daubert* briefing. MDL ECF No. 955, Def. Med. Experts Reply at 42-48. While Plaintiffs’ *counsel* later repudiated the Augustine publication, none of their *experts* has done so. As recently as his February 19, 2019 deposition in *Trombley*, Dr. Jarvis again cited the Augustine 2017 publication (as well as the existence of the MDL itself) as proof of an association between the Bair Hugger system and infections.

Q. When you say “various case reports document the increased risk of SSI”, what -- what are those various case reports?

MR. BEN GORDON: Objection to form and beyond the scope of this deposition.

A The cases we've been involved in, as well as Augustine's report.

Q. By Augustine's report, you mean his report where he compared three different hospitals?

A. Right.

Hulse 3d Recon. Decl. DX21, Jarvis Dep. (*Trombley*) at 62:8-18.

Apart from Augustine's fraudulent publication, Plaintiffs have not identified other data associating the Bair Hugger system with increased risk of infection. Without a reliable study finding an association, an expert cannot reliably apply the Bradford Hill criteria. As the Fourth Circuit observed in affirming exclusion of Plaintiffs' causation expert in *Lipitor*:

The Reference Manual on Scientific Evidence stresses that it is proper to employ the Bradford Hill criteria "only *after* a study finds an association to determine whether that association reflects a true causal relationship.' . . . In fact, the Manual highlights cases in which "experts attempted to use these guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association," but observes that while "[t]here may be some logic to that effort . . . it does not reflect accepted epidemiologic methodology."

Lipitor, 892 F.3d at 640 (emphasis in original; quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* (3d ed. 2011) at 598-99 & n.141).

Plaintiffs' experts' continued reliance on Augustine's fraudulent publication is also powerful evidence of how they have approached their roles as litigation experts. It is difficult to believe that any of them would have relied upon Augustine's publication in their non-litigation work. No one else in the scientific and medical community has relied on it. Plaintiffs' science is manufactured for the courtroom. It is not real science, it is not reliable, and it should be excluded. *See Lipitor*, 892 F.3d at 647 (noting that *Daubert*

“teaches that judges should look beyond the confines of the courtroom to ask what experts do in the real world”).

CONCLUSION

For these reasons, as well as the reasons discussed in Defendants’ Memorandum and Reply, the Court should grant Defendants’ Motion for Reconsideration, exclude Plaintiffs’ medical causation experts, and grant summary judgment for Defendants on all cases in the MDL.

Dated: May 16, 2019

Respectfully submitted,

s/Benjamin W. Hulse

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